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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/17/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,921

Applicant(s)

BATRA ET AL.

Examiner

Shahnam Sharareh

Art Unit

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.*

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/06/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 24-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-44 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 18, 2003 has been entered.

Claims 1-16, 24-44 are pending. Any rejection that is not addressed in this Office Action is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15, 24-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi in view of Remington: the Science and Practice of Pharmacy 19th edition (pages 1616-1620) (IDS, filed June 28, 2001).

Makooi discloses compressed efavirenz tablets comprising 300mg of efavirenz (50% by wt), sodium lauryl sulfate which is a surfactant, microcrystalline cellulose which is a filler, croscarmellose sodium which is a superdisintegrant/disintegrant, lactose which is a filler/compression aid and magnesium stearate which is a lubricant (see abstract; col 5, lines 16; col 7, lines 15-67; claims 12-15). Makooi teaches higher concentrations of efavirenz of up to 800 mg per tablet (see col 5, lines 36-39; claim 14). Makooi employs a wet granulation process to prepare his formulations (see col 5, lines 59-col 6, line 9; example 3). Makooi's methods employs the same steps as the instantly taught, therefore, the final product of Makooi inherently contains and meets all limitations of the instant tablets.

Further, with respect to claims 37-39 Examiner states that the instant claims appear to be drafted as "product by process" claims. Accordingly, products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Accordingly, Makooi's tablets meet the limitations of the instant tablets. Makooi fails to specifically employ 1-5 percent superdisintegrant or employ hydroxypropylcellulose as a binder.

Remington provides teachings for various types of pharmaceutically acceptable excipient that may be used to formulate compressed tablets (pages 1616-1620). For example, Remington on page 1618 sets forth binders such as various types of cellulose derivatives including hydroxypropylcellulose, or other types of binders such as starch or PVP are recognized in the art as art equivalent.

Although Makooi's teachings does not specifically teach the instant concentrations of superdisintegrants/disintegrants or the use of hydroxypropylcellulose as the binder of choice, it would have been obvious to one of ordinary skilled in the art of dosage formulation to optimize the individual ingredients of Makooi's dosage forms by routine experimentation and further substitute any suitable art equivalent moiety known in the art such as hydroxypropylcellulose, as taught in Remington, for the binder of Makooi and improve the pharmacokinetic characteristics of Makooi's dosage formulation.

Response to Arguments

Applicant's arguments filed on March 18, 2003 have been fully considered but they are not persuasive. Applicant argues that Makooi does not teach the instant amount of superdisintegrant. However, applicant's position is based on an illusory distinction between the scope of the instant disintegrants and superdisintegrants.

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Attention is drawn to the scope of the instant claim 1. The instant tablet must contain both disintegrant and superdisintegrant. Page 3 of the specification defines the scope of disintegrants and superdisintegrants. Accordingly, superdisintegrants include and encompass all disintegrants listed in the instant specification (see page 3, lines 8-13, and lines 23-26). Thus, there is no distinction between the instant disintegrant and superdisintegrants. Subsequently, the instant range of superdisintegrants in claim 1 is illusory because it can be modified to a higher percentage if the disintegrant employed is the same as the superdisintegrant.

Declaration Under 37 CFR 1.132

The Declaration under 37 CFR 1.132 filed In October 2003 is sufficient to overcome the rejection of claim 16 based upon the results. However, the declaration is not commensurate with the scope of all other pending claims.

Claim Objection

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claim 16 is free of art in view of the unexpected results presented in the declaration under 37 CFR 1.132 filed on Oct 06, 2003.

Claim 16 would be allowable if rewritten or amended to overcome the objection, set forth in this Office action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS


RUSSELL TRAVERS
PRIMARY EXAMINER